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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/681,303 | 03/15/2001 | Samuel F. Liprie | INE-0044-C2 | 9542 |

23413 7590 04/08/2003

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| EXAMINER |
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KEITH, JACK W

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3641 | 15 |

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/681,303

Applicant(s)

Liprie

Examiner
Jack Keith

Art Unit
3641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Feb 6, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-31 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/6/2003 have been fully considered.

Regarding the 112, first paragraph rejection of the specification and claims relating to the elected embodiment of figure 3 the rejection is withdrawn. Although, it dose appear that the embodiment of figure 3 is counterproductive to the maneuverability of the source wire within the human body in comparison to that of the embodiments of figures 1 and 2.

The claim objection in regard to claim 14 is withdrawn.

Applicant's arguments regarding the 112, second paragraph rejection are not persuasive.

The 112, second rejection of Paper no. 12 is herein incorporated.

Applicant argues that the limitation "when bent" is not a temporal limitation, but rather a limitation that serves to define a characteristic of the materials of the source wire. Clearly, the limitation as set forth in the claim implies how and in what manner the source wire is operated. As set forth in applicant's arguments "the wire *could be* presently bent or straight" (i.e., when claimed). Nonetheless In re Collier, 158 USPQ 266 is appropriate as such statement (i.e., "when bent") is nothing more than the capability of a structure. This capability only resulting by the performance of future acts.

Applicant's arguments regarding the 102 and 103 rejections are not persuasive. The 102 and 103 rejections of Paper no. 12 are herein incorporated.

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Applicant argues that Liprie ('781) fails to teach a housing tube constructed of a shape memory alloy or a capsule inserted into the proximal end of the housing tube.

The examiner disagrees. With regard to the shape memory alloy teachings Liprie ('781) is inherently capable of meeting applicant's claimed inventive concept. Liprie ('781) discloses *Stainless steel, tantalum and titanium* as housing materials. *Stainless steel* or *tantalum* are material equivalents for Nitinol® this is evident by Nariciso et al (5,454,794). Referring to column 3, lines 35-40 Nariciso discloses/teaches that deflecting wires can be fabricated from metals having tensile strength and memory to deflect and return to their original position such as Nitinol®, stainless steel or tantalum.

Further note that Ti-Ni or Ni-Ti alloys are well known within the medical guide wire art. This is evident by the teachings of Ishibe et al (5,230,348) which teaches the desired shape memory characteristics of the alloy and the advantages of such when navigating through blood vessels (i.e., navigate tortuous regions).

The use of a secondary reference in connection with a 35 U.S.C. 102 rejection is proper when the secondary reference is cited to show that the primary reference contains an "enabling disclosure". See MPEP § 2131.01.

Regarding Liprie ('781) failing to teach a capsule inserted into the proximal end of the housing tube. The examiner again disagrees. As set forth previously Liprie ('781) discloses that it is well known (i.e., conventional) within the art to encapsulate the radiation source in a material such as stainless steel (see column 4, lines 10+) to prevent the flaking of the radiation

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source and to provide such sources with radiopaque markers so as to observe the source with fluoroscopy (see column 16, lines 64+). Applicant argues that the selected passage refers only to the indicated prior art of record for Liprie ('781). The examiner disagrees. Prior art referred to in a reference patent may be used for what it fairly teaches. See In re Fortress and Schoeneberg, 152 USPQ 13. Furthermore, there is no indication within the passage that the referenced prior art refers to only Van't Hooft (4,861,520). The prior art referenced could be referring to the inventor's own personal knowledge.

Applicant argues the 103 rejection utilizing Nariciso and/or Ishibe citing that the examiner inappropriately generalizes the equivalents of different metals.

The examiner disagrees. The examiner has clearly set forth a teaching in the prior art that Stainless steel and tantalum are known equivalents to that of Nitinol as set forth by Nariciso. Applicant is questioning the operability/enablement of the reference. When the reference relied upon in the rejection anticipates or makes obvious all the elements of the claimed invention, the reference is presumed to be operable/enabled. Once such a reference is found the burden is on the applicant to provide facts to rebut the presumption of operability/enablement. See In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Also see MPEP § 2121. Applicant has had the opportunity to provide experimental evidence (i.e., test results between the exact same source wires constructed of Nitinol, stainless steel and tantalum) to rebut the Nariciso reference in not only this case, but the other pending cases 09/455579, 09/445582, etc. and has yet to do so. Accordingly, unless provided the Nariciso reference has been appropriately applied.

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Applicant's arguments to the 103 rejection utilizing Suthanthiran or Liprie ('300) are not directed to the rejection set forth in Paper no. 12 (i.e., teaching of a rounded capsule). Accordingly, the primary reference (Liprie ('781)) as set forth above reads on applicant's claimed inventive concept.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Keith whose telephone number is (703) 306-5752. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Carone, can be reached on (703) 306-4198. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7687.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

Jack Keith
Examiner,
Art Unit 3641

jwk

April 4, 2003

MICHAEL J. CARONE
SUPERVISORY PATENT EXAMINER